

WHAT IS CLAIMED IS:

1 1. A method for treating a mammal bearing one or more tumors, said
2 mammal having a prolactin and a melatonin daily rhythm and in need of such treatment
3 comprising the steps of:

4 comparing the prolactin profile of said tumor bearing mammal to a
5 normal prolactin profile for healthy mammals of the same species and sex;

6 adjusting the prolactin profile of the mammal by administering prolactin
7 enhancers or reducers in order that said prolactin profile conforms to or approaches the
8 normal prolactin profile for healthy members of the same species and sex of said mammal;

9 contacting the cells of said tumor with a photosensitizer; and
10 exposing said contacted tumor cells to light of a predetermined
11 wavelength and power density and energy level.

12 2. The method of claim 1 wherein said comparing step further comprises
13 measuring the blood prolactin level of said tumor bearing mammal at spaced apart intervals
14 within a 24-hour period to generate a prolactin profile for said mammal.

15 3. The method of claim 2 wherein said comparing step reveals that said
16 tumor bearing mammal has (i) blood prolactin levels lower than 1 standard error of the mean
17 (SEM) below the normal night time prolactin level at two spaced apart time intervals or (ii)
18 a blood prolactin level lower than 2 SEM below the normal night time prolactin level at one
19 time point; and

6 said adjusting step comprises administering to said tumor bearing
7 mammal a prolactin enhancer at a predetermined time or times to increase the night time
8 prolactin levels of said mammal so that said mammal's night time prolactin level conforms
9 to or approaches the normal night time prolactin profile.

1 4. The method of claim 3 wherein said prolactin enhancer is a member
2 selected from the group consisting of melatonin, metoclopramide, domperidone and 5-
3 hydroxytryptophan.

4 5. The method of claim 3 wherein said tumor bearing mammal is a human.

5 6. The method of claim 5 wherein said prolactin enhancer is melatonin and
6 said melatonin is administered in amount within the range of 0.5-20 mg/person/day.

7 7. The method of claim 1 wherein said adjustment is continued until the
8 prolactin rhythm of said mammal is reset to conform to or approach the normal prolactin
9 profile and continues in its reset condition after cessation of said adjustment.

1 8. The method of claim 2 wherein said adjusting step comprises
2 administering to said tumor bearing mammal a prolactin reducer at a predetermined time or
3 times to decrease the day time prolactin levels of said mammal so that said mammal's day
4 time prolactin level conforms to or approaches the normal night time prolactin profile.

1 9. The method of claim 8 wherein said mammal is a human, said prolactin
2 reducer is bromocriptine, said bromocriptine is administered in an amount within the range
3 of 0.2 to 8.0 mg/person/day, and said predetermined time is between about 6:00h and
4 10:00h.

1 10. The method of claim 9 wherein said bromocriptine is administered in
2 an amount within the range of 0.8 to 4.8 mg/person/day.

1 11. The method of claim 10 wherein said bromocriptine amount is within
2 the range of 0.8 - 3.2 mg/person/day.

1 12. The method of claim 6 wherein said predetermined time is about
2 bedtime.

1 13. The method of claim 1 wherein said photosensitizer:
2 is positively charged;
3 is sufficiently lipophilic to be taken up by said tumor;
4 is retained substantially longer in the cells of said tumor than in non-
5 tumor cells;
6 has a high absorption coefficient in the 600-900 nm light spectral
7 region;
8 is capable of sensitizing tumor cells to killing by light exposure; and
9 is administered in an effective amount to sensitize said tumor to light.

1 14. The method of claim 13 wherein said photosensitizer is selected from
2 the group consisting of porphyrin dyes, phthalocyanine dyes, cyanine dyes, benzophenoxazine
3 analogs, and pharmaceutically acceptable salts thereof.

1 15. The method of claim 13 wherein said prolactin reducer or enhancer is
2 administered orally, by injection, transdermally, or intranasally.

1 16. The method of claim 13 wherein said photosensitizer is administered
2 intravenously, intraperitoneally, subcutaneously, or intralesionally.

1 17. The method of claim 16 wherein said effective amount of said
2 photosensitizer is between about 0.1 and 15 mg/kg of body weight.

1 18. The method of claim 16 wherein said effective amount is between about
2 0.5 and 10 mg/kg of body weight.

1 19. The method of claim 18 wherein:
2 the energy level of said light is between about 5 and 400 Joules/cm²;
3 the power density of said light is between about 50 and 200
4 mWatts/cm²;
5 said tumor cells are exposed to said light between about 0.5 and 8 hours
6 after administration of said photosensitizer.

1 20. The method of claim 16 wherein said effective amount is about 5.0
2 mg/kg of body weight.

1 21. The method of claim 19 wherein:
2 the energy level of said light is about 100 Joules/cm²;
3 the power density of said light is about 50 mWatts/cm²;
4 said tumor cells are exposed to said light at about 1 hour after
5 administration of said photosensitizer.

22. The method of claim 19 wherein said photosensitizer is a
benzophenothiazine.

23. The method of claim 21 wherein said photosensitizer is a
benzophenothiazine.

24. The method of claim 22 wherein said benzophenothiazine is a member
2 selected from the group consisting of Dye 4-115 and 5-ethylamino-9-diethylamino-
3 benzo[a]phenothiazinium chloride.

1 25. The method of claim 23 wherein said benzophenothiazine is a member
2 selected from the group consisting of Dye 4-115 and 5-ethylamino-9-diethylamino-
3 benzo[a]phenothiazinium chloride.

1 26. The method of claim 13 wherein said contacting and exposing steps
2 occur between about 7 and 14 days after initiation of said adjusting step.

1 27. The method of claim 15 wherein:
2 said mammal is a human;
3 said prolactin reducer is bromocriptine; and
4 said prolactin enhancer is selected from the group consisting of
5 prolactin, melatonin, metoclopramide, domperidone, and 5-hydroxytryptophan.

1 28. The method of claim 27 wherein said prolactin enhancer is selected
2 from the group consisting of prolactin and melatonin.

1 29. The method of claim 27 wherein said bromocriptine is administered at
2 a time between about 6:00h and 10:00h and in an amount between about 0.8 and 8.0
3 mg/person/day.

1 30. The method of claim 28 wherein said prolactin enhancer is melatonin
2 and wherein said melatonin is administered at about bedtime and in an amount between about
3 0.5 and 20 mg/person/day.

1 31. The method of claim 29 wherein:
2 the energy level of said light is about 100 Joules/cm²;
3 the power density of said light is about 50 mWatts/cm²;

4 said tumor cells are exposed to said light at between about 1 and about
5 3 hours after administration of said photosensitizer;

6 said photosensitizer is a member selected from the group consisting of
7 Dye 4-115 and 5-ethylamino-9-diethylamino-benzo[a]phenothiazinium chloride; and

8 said photosensitizer is administered in an amount between about 1 and
9 5 mg/kg of body weight.

1 32. The method of claim 30 wherein:

2 the energy level of said light is about 100 Joules/cm²;

3 the power density of said light is about 50 mWatts/cm²;

4 said tumor cells are exposed to said light at between about 1 and about
5 3 hours after administration of said photosensitizer;

6 said photosensitizer is a member selected from the group consisting of
7 Dye 4-115 and 5-ethylamino-9-diethylamino-benzo[a]phenothiazinium chloride; and

8 said photosensitizer is administered in an amount between about 1 and
9 5 mg/kg of body weight.

1 33. A method for treating a mammal bearing one or more tumors, said
2 mammal having prolactin and melatonin daily rhythms and in need of such treatment
3 comprising the steps of:

4 adjusting the prolactin and melatonin profiles of the mammal by
5 administering prolactin enhancers or reducers and melatonin in order that said prolactin and

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